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Attorneys for Plaintiffs
SPECTRUM PHARMACEUTICALS, INC.
AND UNIVERSITY OF STRATHCLYDE

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

SPECTRUM PHARMACEUTICALS, INC. and UNIVERSITY OF STRATHCLYDE, Plaintiffs, v. BEN VENUE LABORATORIES, INC. d/b/a BEDFORD LABORATORIES Defendants.	Case No.: 2:14-cv-00980 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Spectrum Pharmaceuticals, Inc. ("Spectrum") and University of Strathclyde ("Strathclyde") (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Ben Venue Laboratories, Inc. ("Ben Venue"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arising from Ben Venue's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market a levoleucovorin product, which is a generic form of Spectrum's pharmaceutical product Fusilev®, prior to the expiration of United States Patent No. 6,500,829 ("the '829 patent"), which covers Fusilev®.

THE PARTIES

2. Spectrum is a Delaware corporation having its principal place of business at 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Spectrum is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. Strathclyde, incorporated by Royal Charter of Queen Elisabeth II, is a charitable body registered in Scotland with registration number SC015263, having its principal place of business at 16 Richmond Street, Glasgow G1 1XQ, Scotland, United Kingdom.

4. Upon information and belief, Bedford Laboratories ("Bedford") is an unincorporated division of Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of the State of Delaware, both having a place of business at 300 Northfield Road, Bedford, Ohio 44146.

5. Upon information and belief, Ben Venue, directly and/or through Bedford, markets, manufactures, distributes, and sells generic drugs for use in the State of Nevada and throughout the United States.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C.

§§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Ben Venue. Ben Venue has purposefully conducted and continues to conduct business in this District, including by having availed itself of the rights, protections, and benefits of Nevada law, such that it should reasonably anticipate being haled into court in this District.

8. On information and belief, Ben Venue through Bedford applied for, and received a license from the Nevada Board of Pharmacy to act as a pharmaceutical wholesaler in Nevada. On information and belief, Ben Venue through Bedford is currently a registered "Wholesaler" of drug products with the Nevada Board of Pharmacy, and distributes drug products throughout the State of Nevada. Ben Venue directly and/or through Bedford has systematic and continuous contacts with the State of Nevada, by including, among other things, selling pharmaceutical products to residents of Nevada, and to others with the intent that those products are marketed and distributed in Nevada, and receiving significant revenue for the sale of those products in Nevada.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

THE PATENT-IN-SUIT

10. On December 31, 2002, the United States Patent and Trademark Office issued U.S. Patent No. 6,500,829, entitled “Substantially Pure Diastereoisomers of Tetrahydrofolate Derivatives.” At the time of its issue, the ‘829 patent was assigned to Strathclyde. Strathclyde currently holds title to the ‘829 patent. Strathclyde has exclusively licensed the ‘829 patent to Spectrum. A copy of the ‘829 patent is attached hereto as Exhibit A.

11. The claims of the ‘829 patent are valid and enforceable.

FUSILEV®

12. Spectrum holds New Drug Application No. 20-140 (initially approved on March 7, 2008) (“the Fusilev® NDA”) approving Spectrum to market a levoleucovorin product as a lyophilized powder in a 50 mg dosage strength, which is marketed by Spectrum under the trade name Fusilev®.

13. On November 7, 2011, the FDA granted Fusilev® seven years of orphan-drug

exclusive approval pursuant to Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360cc) for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of advanced metastatic adenocarcinoma of the colon and rectum.

14. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '829 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") with respect to Fusilev®.

BEN VENUE'S ANDA

15. On information and belief, Ben Venue submitted an Abbreviated New Drug Application, ANDA No. 206263, to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market levoleucovorin calcium for injection, 50 mg/vial ("Ben Venue's ANDA"). The levoleucovorin vial described in Ben Venue's ANDA are herein referred to as "Ben Venue's Product."

16. On information and belief, Ben Venue's ANDA refers to and relies upon the Fusilev® NDA and/or the Fusilev® sNDA and contains data that, according to Ben Venue, demonstrates the bioequivalence of Ben Venue's Product and Fusilev®.

17. By filing Ben Venue's ANDA, Ben Venue has necessarily represented to the FDA that Ben Venue's Product has the same active ingredient as Fusilev®, has the same route of administration, dosage form, and strength as Fusilev®, is bioequivalent to Fusilev®, and has the same or substantially the same proposed labeling as Fusilev®.

18. Spectrum received a letter from Ben Venue on or around June 11, 2014 ("Ben Venue's Notification"), stating that Ben Venue had included a certification in Ben Venue's ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '829 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Ben Venue's Product.

19. This action is being brought within forty-five days from the date that Spectrum received Ben Venue's Notification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,500,829

20. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-19

of this Complaint.

21. The '829 patent contains claims directed to, for example (claim 1), "A pharmaceutical composition for therapeutic use which consists essentially of a therapeutically effective amount sufficient for the treatment of human beings for methotrexate rescue or folate deficiency, of a pharmaceutically acceptable compound which is a (6S) diastereoisomer selected from the group consisting of (6S) leucovorin (5-formyl-(6S)-tetrahydrofolic acid) and pharmaceutically acceptable salts and esters of (6S) leucovorin; wherein the compound consists of a mixture of (6S) and (6R) diastereoisomers and consists of at least 92% by weight of the (6S) diastereoisomer, the balance of said compound consisting of the (6R) diastereoisomer; in combination with a pharmaceutically acceptable carrier."

22. Ben Venue infringes claims 1 and 2 of the '829 patent, and does not deny such infringement in Ben Venue's Notification.

23. Ben Venue has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A) by submitting Ben Venue's ANDA, by which Ben Venue seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Ben Venue's Product prior to the expiration of the '829 patent.

24. Ben Venue's commercial manufacture, use, offer to sell, or sale of Ben Venue's Product within the United States, or importation of Ben Venue's Product into the United States, during the term of the '829 patent would further infringe one or more claims of the '829 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

25. Ben Venue's filing of Ben Venue's ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Ben Venue's Product upon receiving FDA approval creates an actual case or controversy with respect to infringement of the '829 patent.

26. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval relating to Ben Venue's ANDA shall not be earlier than March 7, 2022, the current expiration date of the '829 patent, or any later expiration date to which Plaintiffs become entitled.

27. This is an exceptional case, and Plaintiffs are entitled to an award of attorneys' fees, under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that this Court grant the following relief:

A. A declaration that the '829 patent is valid and enforceable;

B. A declaration that by filing Ben Venue's ANDA, Ben Venue has infringed one or more claims of the '829 patent under 35 U.S.C. § 271(e)(2)(A);

C. A declaration that one or more claims of the '829 patent would be infringed by the manufacture, use, offer for sale, or sale of Ben Venue's Product within the United States, or by importation of Ben Venue's Product into the United States;

D. An Order preliminarily and permanently enjoining Ben Venue, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Ben Venue's Product within the United States, or importing Ben Venue's Product into the United States, prior to the expiration of the '829 patent (including any extensions thereof);

E. An Order prohibiting Ben Venue, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining approval of Ben Venue's ANDA, prior to the expiration of the '829 patent (including any extensions thereof);

F. A declaration that the effective date of any approval of Ben Venue's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '829 patent (including any extensions thereof);

G. A judgment awarding Plaintiffs damages or other monetary relief if Ben Venue commercially manufactures, uses, offers to sell, or sells Ben Venue's Product within the United States, or imports Ben Venue's Product into the United States, prior to the expiration of the '829 patent (including any extensions thereof), and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

H. A declaration that this is an exceptional case and a judgment awarding Plaintiffs

their reasonable attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285 and 271(e)(4);

I. Reasonable filing fees, costs and expenses incurred by Plaintiffs in this action; and

J. Such further and other relief as this Court deems just and proper.

Dated: this 18th day of June, 2014.

Respectfully submitted,

LEWIS ROCA ROTHGERBER LLP

By: /s/ Mark H. Izraelewicz

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